Exhibit 11

EXHIBIT A

TEVA Americas Generics

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Re: ANDA No. 77-530—Valsartan Tablets, 40 mg, 80 mg, 160 mg, and 320 mg

I write regarding the above-referenced ANDA ("the Teva ANDA"), which is caught up in an unusual, perhaps even unique, situation. FDA has not approved Teva's ANDA, despite the expiration of the last patent-based obstacle to approval more than a year ago, apparently based on the view that Ranbaxy Laboratories Ltd. holds the first substantially complete ANDA for this product (No. 77-492, or "the Ranbaxy ANDA"). Yet Ranbaxy has thus far failed to obtain final approval and to launch its product. The reason presumably relates to the well-documented problems at several Ranbaxy facilities, including serious data-integrity violations. The Ranbaxy ANDA thus is preventing approval of numerous other ANDAs, including the Teva ANDA. And none of the usual mechanisms for eliminating this sort of bottleneck appears to apply in this situation. As a result of Ranbaxy's problems, the holder of the reference listed drug, Diovan®, still faces no generic alternatives, it has raised the price since the patent-related stay expired, and consumers have already lost about $900 million in potential cost savings.[1] This is an unprecedented set of circumstances. Given the impact on consumers, we felt it was important to raise this issue with FDA and to offer our help and guidance.

Teva submits that recent developments under the Ranbaxy consent decree have opened a way forward for FDA. The information that has come to light about Ranbaxy casts significant doubt on Ranbaxy's status as a "first-filer" entitled to exclusivity. An ANDA that includes unreliable data developed at a tainted facility is not, and never was, substantially complete. And the list of Ranbaxy's tainted facilities has grown. Just in the last few months, FDA has barred from the U.S. market any drug that was manufactured at, or uses material from, Ranbaxy's Toansa facility—the very facility at which Ranbaxy apparently intended to manufacture the active pharmaceutical ingredients (API) for valsartan tablets.[2] Under the consent decree, the newly designated facility must be treated "as though it . . . were listed . . . when the Decree was entered." Decree ¶ XXIX. Those violations cast serious doubt on whether Ranbaxy could, in fact, have been the first to file a substantially complete ANDA.

We are confident that FDA would not approve an ANDA for a product that Ranbaxy actually contemplated manufacturing at a tainted facility. But our concern is not limited to final approval. Treating Ranbaxy as the first-filer when it cannot obtain final approval serves to block the path to approval for others. And even if Ranbaxy *can* obtain final approval, that does not eliminate the need to scrutinize its original ANDA filing. Even if Ranbaxy *now* can find another facility, or a business partner, that is not enough to show that Ranbaxy was entitled to exclusivity

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[1] *See* Makiko Kitamura, *Ranbaxy's Woes Add $900 Million to U.S. Heart Drug Costs*, Bloomberg News, Apr. 15, 2014, http://www.bloomberg.com/news/2014-04-15/ranbaxy-s-woes-add-900-million-to-u-s-heart-drug-costs.html.
[2] *See* Anmol Ganjoo, *Ban may hit Ranbaxy's new product launches: JM Fin*, moneycontrol.com, Jan. 24, 2014, http://www.moneycontrol.com/news/market-outlook/ban-may-hit-ranbaxys-new-product-launches-jm-fin_1030820.html.

in the first place. Rather, the crucial question is whether, *with all tainted data excluded*, Ranbaxy's ANDA for valsartan tablets was substantially complete when filed.

We therefore ask that FDA move expeditiously—if it has not already—to assess whether the Ranbaxy ANDA is properly viewed as having been substantially complete when filed. Assuming that FDA's investigation confirms our suspicion that the Ranbaxy ANDA contains tainted data, we request that FDA: (1) approve the Teva ANDA immediately; (2) award Teva the first-filer exclusivity on the ground that it was the first generic applicant to submit a substantially complete ANDA for this product; and (3) not approve any other ANDAs for this product until 181 days after Teva's launch, except for other ANDAs (if any) that were substantially complete and filed on the same day as the Teva ANDA.

Background on Valsartan Tablets

Much of the background information appears in FDA's letter tentatively approving the Ranbaxy ANDA (attached as Exhibit 1). Valsartan is an Angiotensin II Receptor Blocker used primarily to treat hypertension by lowering blood pressure. Valsartan is marketed in tablet form by Novartis Pharmaceuticals Corp. under the brand name Diovan Tablets (NDA 21-283, approved July 8, 2001). In the absence of generic competition, Diovan retails for well over $100 for a 30-day supply. According to Novartis's annual report, 2013 revenue from Diovan exceeded $1.5 billion for U.S. sales alone.

The *Orange Book* currently lists two patents for Diovan:

- U.S. Patent No. 6,294,197 (the '197 patent), which expires June 18, 2017; and
- U.S. Patent No. 5,972,990 (the '990 patent), which expires October 26, 2016.

A third patent, U.S. Patent No. 5,399,578 (the '578 patent), was previously listed, but that patent expired March 21, 2012. Pediatric exclusivity expired September 21, 2012.

FDA has granted tentative approval to eight pending ANDAs for valsartan tablets, but has not granted final approval to any of them. The Ranbaxy ANDA is dated December 24, 2004, and received tentative approval on October 25, 2007. The Teva ANDA appears to be next: it was filed on January 7, 2005, and first received tentative approval on June 10, 2008. It appears that the two listed patents are no obstacle to approving either the Ranbaxy ANDA or the Teva ANDA.

With respect to the '197 patent, both Ranbaxy and Teva filed Paragraph IV certifications under Section 505(j)(2)(A)(vii)(IV) of the FDCA, stating that the patent is invalid, unenforceable, or would not be infringed under the Ranbaxy or Teva ANDAs. Ranbaxy and Teva have both informed FDA that they provided Novartis with proper notice of the Paragraph IV certifications, and Novartis did not sue within 45 days to enforce the '197 patent against either Ranbaxy or Teva. Accordingly, it appears that pursuant to Section 505(j)(5)(B)(iii), the '197 patent does not prevent FDA from approving either of these ANDAs.

With respect to the '990 patent, through a use code in the *Orange Book*, Novartis claims only a particular use, *i.e.*, use of valsartan to reduce cardiovascular mortality in certain groups of

patients. Both Ranbaxy and Teva filed statements pursuant to Section 505(j)(2)(A)(viii) of the Act indicating that they do not seek approval for any indication claimed by the patent. Accordingly, it appears that the '909 patent also does not prevent FDA from approving either of these ANDAs.

Because the patents do not prevent FDA from approving the Teva ANDA, Teva can only conclude that the obstacle preventing approval is a potential grant of first-filer exclusivity under Section 505(j)(5)(B)(iv) to Ranbaxy, which has not yet expired or been forfeited. We are not aware that any event that would give rise to forfeiture under Section 505(j)(5)(D)(i) has occurred.

Ranbaxy's Violations of the FDCA

In a series of actions, culminating in the entry of a consent decree in 2012 and a guilty plea in 2013, FDA has determined that Ranbaxy has committed multiple violations of the FDCA, including violations that tainted a number of Ranbaxy's ANDAs. The consent decree makes clear that FDA may determine, after factual investigation, that one or more of Ranbaxy's ANDAs was not "substantially complete" when filed, because of the inclusion of data from a tainted facility. Particularly in light of the recently identified problems at the Toansa facility, there is a significant possibility that the Ranbaxy ANDA for valsartan tablets was not substantially complete and that Ranbaxy is not entitled to exclusivity at all.

The government told the United States District Court in a civil complaint under the Food, Drug and Cosmetics Act (FDCA) that Ranbaxy "ha[s] had a persistent problem with data integrity." Complaint ¶ 32. According to the government's complaint, Ranbaxy has "submitted numerous untrue statements of material fact in submissions to FDA." *Id.* In addition, the government charged, Ranbaxy has used "inadequate control measures for insuring the integrity of data." *Id.* Among these violations were several instances in which Ranbaxy deleted failing test results and tested and re-tested samples until it achieved the result it sought.

Of primary significance here, the consent decree provides that FDA will stop reviewing any ANDA that "contains any data or information generated or developed at" two facilities covered by the decree, Paonta Sahib and Dewas Consent Decree ¶¶ VII.F, .G, XVII, *United States v. Ranbaxy Labs., Ltd.*, No. 12-CV-250 (D. Md.). Such ANDAs will not be reviewed or approved unless and until FDA's concerns about the reliability of the data are resolved through a number of specific auditing steps involving an outside data-integrity expert. *Id.* ¶ XVII.

The consent decree also recognizes that FDA, the data-integrity expert, or both might discover that Ranbaxy's pattern of data irregularities extended to other facilities as well. *See id.* ¶¶ XVII.D, XXIX. Accordingly, the decree provided that if FDA identified other Ranbaxy facilities giving rise to "an untrue statement" or a "pattern and/or practice of data irregularities affecting approval," FDA could bring those facilities under the Consent Decree. *Id.* ¶ XXIX. If FDA issues such an order, the designated facility or facilities "shall thereafter be fully subject to the provisions of this Decree as though it or they were listed as a Covered Facility . . . when the Decree was entered." Thus, if a new facility is added to the decree's coverage later, ANDAs tainted by work performed at that newly added facility are not grandfathered in; they are fully subject to the Decree's requirements.

A few specified ANDAs—the identities of which are not public—are excepted from the hold that the decree imposed on ANDAs tainted by Paonta Sahib and Dewas. Those ANDAs are called "Excepted Applications," and Ranbaxy is required to establish in writing to FDA's satisfaction "whether the Excepted Applications were substantially complete . . . at the time they were initially filed." *Id.* ¶ VII.H, XIV. If the evidence shows that data contained in one of these ANDAs as submitted was tainted, then under the terms of the Consent Decree FDA is empowered to determine that the ANDA was *not* substantially complete at the time it was filed, whether or not the ANDA appeared on its face to be complete. Ranbaxy would be "ineligible for exclusivity for such ANDA." *Id.* ¶ XIV.A.2.

In January 2014, FDA added Ranbaxy's facility at Toansa, India, to the decree's coverage. FDA found numerous violations at that facility, including various instances of "retesting" items "after those items failed analytical testing and specifications, in order to produce acceptable findings, and subsequently not reporting or investigating these failures." FDA Press Release (Jan. 23, 2014). As noted above, *supra* note 2, it had been widely reported that Ranbaxy planned to manufacture its generic valsartan tablets using API from Toansa. FDA's decision to bar from the United States any product tainted by association with Toansa has now called Ranbaxy's plans into serious question. Under the provisions of the consent decree cited above, if the evidence demonstrates that Ranbaxy's valsartan ANDA contained tainted data from Toansa (or any other Ranbaxy facility covered by the decree), FDA should determine that Ranbaxy's ANDA was not substantially complete when filed and that Ranbaxy is not eligible for exclusivity for that ANDA.

Requirement to Determine Exclusivity

Although the contents of Ranbaxy's ANDA are not publicly available, Ranbaxy's conduct gives rise to grave concern about the validity of its initial ANDA submission—the submission that, while not yet approved, appears to be blocking seven other generics from the market. In particular, because Ranbaxy's ANDA was dated December 24, 2004, and amended several times leading up to tentative approval on October 25, 2007, it appears that it likely was based on data developed during the period of time during which—to use FDA's characterization—Ranbaxy was having "a persistent problem with data integrity." If Ranbaxy's ANDA was in fact tainted by data-integrity problems, it very likely was not substantially complete when it was filed. As a consequence, the Ranbaxy ANDA should not block approval of the Teva ANDA, and Ranbaxy's tainted filing should not deprive Teva of its right to be awarded first-filer exclusivity for the product as the first applicant to have submitted a substantially complete ANDA.

The statutory requirement is clear: FDA cannot award exclusivity to an ANDA applicant without determining the date on which that applicant submitted a "substantially complete" ANDA. The applicant is not a "first applicant," and is not eligible for exclusivity, if another applicant submitted a "substantially complete" ANDA containing a Paragraph IV certification for the same listed drug on an earlier date. *See* FDCA § 505(j)(5)(B)(iv)(II)(bb); 21 C.F.R. § 314.107(c)(2). On the other hand, an applicant whose submission is not substantially complete cannot properly be considered a true first applicant and, thus, cannot prevent the first substantially complete filer from receiving the exclusivity to which the statute entitles it.

An application is not "substantially complete" unless it meets the two statutory criteria. First, it must "on its face" be "sufficiently complete to permit a substantive review." Second, it must "contain[] all the information required by [Section 505(j)(2)(A)]." FDCA § 505(j)(5)(B)(iv)(II)(cc).

An application does not contain all the information required by the FDCA, and thus is not "substantially complete," if it contains forged or fraudulent data about the drug or its manufacture, processing, and packing. The statute, its legislative history, and FDA's consistent practice all make clear that an applicant cannot obtain the benefit of exclusivity if that applicant won the race to file first by making up data.

- *First*, the statute requires that the application "contain[] all the information required by" the statutory provision governing the contents of an ANDA. That provision includes, by cross-reference, the requirement that the ANDA include "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug." FDCA § 505(b)(1)(D); *see* FDCA § 505(j)(2)(A)(vi) (cross-referencing clause (b)(1)(D)). The statute also requires that an ANDA contain "information to show" certain key facts, such as bioequivalence to the reference listed drug. FDCA § 505(j)(2)(A)(i), (ii)(I), (ii)(II), (ii)(III), (iii), (iv), (v). An ANDA cannot provide a "full description" of the manufacturing process, or "information to show" bioequivalence, if the "description" or "information" are fictitious even in part.

- *Second*, the legislative history confirms the common-sense point that Congress did not want to encourage the submission of "sham ANDA's or ANDA's which are substantially incomplete." H.R. Rep. No. 98-857, Pt. I, at 24 (1984). The House Committee Report observed that at a minimum the applicant must have "made a good faith effort to meet the [statutory] requirements . . . regarding the contents of an ANDA." *Id.* It is difficult to imagine conduct *less* likely to qualify as a "good faith effort" than the conscious alteration of data or the knowing submission of tainted data.

- *Third*, Congress adopted the current definition of "substantially complete" against a backdrop of agency practice. One of the most relevant aspects of that practice was FDA's treatment of bioavailability and bioequivalence studies. FDA has provided for many years that an ANDA applicant needs to provide a bioequivalence study as part of its ANDA, or the application ordinarily will not be deemed substantially complete. 21 C.F.R. § 314.107(c)(2). Because a study conducted at a facility with a pattern or practice of data-integrity violations is effectively no study at all, an ANDA submitted with such a tainted study cannot be regarded as substantially complete.

- *Fourth*, the consent decree signed with Ranbaxy resolves any doubt that substantial completeness may be evaluated after problems with an initial submission come to light. The consent decree provides that FDA will evaluate the substantial completeness of Ranbaxy's ANDAs not as of the date they were filed, but as of today, "based on any information" that comes to FDA's attention. Decree ¶ XIV.A.1. Indeed, Ranbaxy is required to make additional written submissions to enable FDA to make that determination. That provision would make no sense if FDA could determine substantial completeness only by looking at the face of the ANDA.

The upshot is clear: if FDA's review of the Ranbaxy ANDA *today*, in light of the recent revelations about the Toansa plant or other Ranbaxy facilities tainted by fraud, demonstrates that the Ranbaxy ANDA did not contain all the actual, non-tainted information required by statute, then the Ranbaxy ANDA was not substantially complete as of the time it was submitted; it is not eligible for an award of exclusivity; and it can no longer block approval of the Teva ANDA.

Requirement To Award Exclusivity To The Rightful First Filer

The consequence of finding that Ranbaxy's ANDA is not substantially complete does not end with ruling that it provides no basis for delaying approval of the Teva ANDA. FDA also must determine which applicant *did* file the first substantially complete ANDA for this product, and award the first-filer exclusivity to that applicant. Here, we believe that the first-filer exclusivity would properly be awarded to Teva.

The statute clearly provides that the exclusivity analysis looks *only* at the first day when a substantially complete ANDA is filed. FDCA § 505(j)(5)(B)(iv)(II)(bb). If an ANDA is *not* substantially complete, it simply drops out of the exclusivity analysis. Conversely, if a Paragraph IV ANDA *is* substantially complete when it is filed, and if it is filed on the first day when a substantially complete ANDA is filed, it does not matter whether another Paragraph IV ANDA was filed on an earlier date but turned out not to be substantially complete. That applicant is entitled to exclusivity, because it unambiguously meets the definition of a "first applicant": "on the first day on which a substantially complete application containing a [Paragraph IV certification] is submitted for approval of [the] drug, [that applicant] submit[ted] a substantially complete application that contain[ed] and lawfully maintain[ed] a [Paragraph IV certification] for the drug." *Id.* The grant of exclusivity is "the device Congress has chosen to induce challenges to patents claimed to support brand drugs." *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1318 (D.C. Cir. 2010). FDA lacks authority to deny an applicant the congressionally prescribed reward.[3]

The addition of the "forfeiture events" to the statute in 2003, *see* FDCA § 505(j)(5)(D), does not change that analysis. FDA can use its power to revoke exclusivity based on a "forfeiture event" only if the applicant properly qualifies for exclusivity in the first place. If an applicant is not a "first applicant"—*i.e.*, if someone else was the first to submit a substantially complete Paragraph IV ANDA—then the forfeiture provisions have no application at all. *See* FDCA § 505(j)(5)(D)(ii) (exclusivity "shall be forfeited *by a first applicant* if a forfeiture event occurs with respect to that *first applicant*") (emphasis added). FDA can take away exclusivity from *everyone* only "if all *first applicants* forfeit" their exclusivity under the statute. FDCA § 505(j)(5)(D)(iii) (emphasis added). If Ranbaxy was never a "first applicant" entitled to exclusivity to valsartan, it cannot have forfeited that exclusivity – and it certainly cannot have forfeited the exclusivity that *Teva* receives as the apparent first applicant. Teva certainly has not done anything to cause a forfeiture.

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[3] Before the *Teva v. Sebelius* decision, in the 1999 *Federal Register* notice discussed above, FDA took the position that if an application were later deemed "not . . . to be substantially complete," FDA could deny the applicant exclusivity *and* deny exclusivity to any other applicant with respect to the same listed drug. *See* 62 Fed. Reg. 42,875. Adopting that position would have been legal error, and we request that the agency confirm that it is not taking that position today.

And FDA is not locked into making a substantial-completeness determination at the time it receives an ANDA. Rather, under the statute, FDA is to make that determination when it sets the effective date for the approval of a *subsequent* ANDA. FDCA § 505(j)(5)(B)(iv). In the case of the numerous ANDAs for valsartan tablets awaiting FDA's approval, that time is now.

Conclusion

In this case, FDA must decide *now* whether there is any reason justifying the continued refusal to approve the Teva ANDA. FDA should accordingly make that decision based on its *present-day* understanding of whether the Ranbaxy ANDA was substantially complete when filed. There is absolutely no reason under the statute, regulations, or agency practice for FDA to blind itself to the last several years of data-integrity problems in Ranbaxy ANDAs. In short, if the Ranbaxy ANDA was deficient when submitted, and if Ranbaxy did not correct the problems with its data until after another applicant submitted a substantially complete ANDA for valsartan tablets, then Ranbaxy is not entitled to exclusivity.

Here Teva did everything right. The Teva ANDA was submitted promptly and with robust data. It appears that only Ranbaxy was ahead of Teva in line. FDA thus must now determine whether Ranbaxy jumped ahead in line by duplicitous means, ie filing an ANDA that was never "substantially complete". If it did, there can be only one conclusion: Teva is entitled to exclusivity as the true first filer (along with anyone else filing an ANDA on the first date when a substantially complete application was received).

Please respond on or before May 15 – and in any event before FDA takes any action to approve an ANDA for valsartan tablets other than the Teva ANDA. We would also welcome the opportunity to discuss these points with you in person at your earliest convenience.

Sincerely,

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